Dahlberg CA, Cusick CP et al. Treatment Efficacy of Social Communication Skills Training After Traumatic Brain Injury: A Randomized Treatment and Deferred Treatment Controlled Trial. Arch Phys Med Rehabil 2007;88:1561-73.

Design: Randomized clinical trial

Population/sample size/setting:

- 52 post-acute moderate to severe TBI patients with some impairment in social communications skills (44 men, 8 women, mean age 41) treated at the research department of Craig Hospital in Colorado
- Eligible patients were between 18 and 65, spoke English, had TBI caused by an external mechanical force, with loss of consciousness, post-traumatic amnesia, skull fracture, or neurological findings attributable to TBI; had been discharged from a TBI rehabilitation program, were at least 1 year post-injury, functioned at or above Rancho Los Amigos Level VI with communication skills and day-to-day recollection sufficient for participation in group activity
- Exclusion criteria were significant behavioral issues precluding group participation (anger control, medical conditions, etc), significant psychiatric disorder, alcohol, or substance abuse; or motor conditions affecting speech

Main outcome measures:

- Randomized to either active treatment (n=26) or delayed treatment (n=26)
- Active treatment group began the program after randomization; the delayed treatment group began the program 12 weeks after randomization, just as the active group was finishing its treatment program
- Active treatment consisted of 12 weekly 90 minute group sessions in a living room-type setting
    - Group program followed a structured workbook designed to develop social communication skills needed for successful interpersonal interactions and relationships, such as nonverbal communication cues, observing social boundaries, understanding others, paying attention, maintaining a conversation, etc
    - Participants were given homework assignments between sessions, and were asked to share the learning materials with family members
    - Groups were limited to 8 participants
- Primary outcome measure was the Profile of Functional Impairment in Communication (PFIC, Linscott et al, 1996), which has 10 scales scored from 0 (no impairment) to 5 (severe impairment); these include logical content, clarity of expression, participation skills, and aesthetics
    - PFIC was scored by blinded assessors who viewed 10 minute videotaped conversations with research assistants who were also blinded to group assignment; these taped conversations were set up as "getting to know one another," and were conducted in the same setting as the group sessions
    - These conversations were done at baseline and again at the end of the 12 week group program; they were repeated at 3, 6, and 9 months after

the end of the 12 week program for the active group (and at 3 and 6 months for the delayed group)

- Several secondary outcome measures were done as well, but these were mostly done by self-report or based on reports of family members
- On 7 of the 10 scales of the PFIC, the treatment group had significantly more improvement than the control group at the end of the 12 week follow-up
    - Larger improvements were seen in the scales in which the impairments were greater at baseline; e.g., a treatment effect was measured for the general participation scale (baseline 2.81) but not for the logical content scale (baseline 0.86)
- Most self-reported secondary outcomes did not show a treatment effect; only one scale, a measure of social communication skills, showed the treatment group experiencing more subjective improvement than the control group
- Subsequent measures of PFIC scores at 3 and 6 months did not show any significant decline from post-treatment, indicating that the gains were maintained at later follow-up

Authors' conclusions:

- Social communication skills training in a group format can improve individual communication deficits in the postacute care of TBI, as assessed by blinded evaluations of videotaped conversations at baseline and follow-up
- Although the treatment effects were less apparent on the multiple self-report and family reported satisfaction measures, these scales may not have been sufficiently sensitive to capture changes in these complex outcomes
- Study limitations include the enrollment which excluded potential participants with psychiatric or substance abuse issues; there was also missing data for some of the PFIC measures, which was the primary outcome measure of the study
    - Although lack of blinding may be a limitation, those involved in the study did not identify any significant bias in the process
    - The PFIC was developed for use with TBI, but there are few published studies in which it was used
- The study only tested the efficacy of 2 group leaders who had more than a decade of developing and refining the treatment intervention; the generalizability of the results is uncertain

Comments:

- Some risks of bias (lack of blinding of participants) are unavoidable, but the blinding of the PFIC assessors who watched the taped conversations is uncertain
    - This bias could have been estimated by asking the assessors to guess which group they thought the participant had been in
    - Since it could be difficult to avoid inadvertent disclosure of treatment group during the taped conversations, asking the assessors to guess at the treatment assignment would have provided valuable information

- The PFIC has 10 scales of which 7 estimated significant treatment effects; in Table 2, it appears highly likely that there were floor effects for some of them
    - That is, the scales which did not show significant improvements or treatment effects were the ones with lower (better) baseline scores, so that improvement is very difficult to achieve
    - The floor effect would not be a weakness of the study, but would tend to bias the treatment effect toward the null value, and does not undermine the conclusions of the study
- Because the PFIC has had limited use in TBI populations, it is not clear what constitutes a clinically important improvement; on a scale with only 5 points, an improvement of 1 point would be reasonable to recognize as important, but smaller average improvements might also be consequential
- Concealment of allocation was not done as part of the randomization; this protects against selection bias, and can be done even when blinding of participants is not possible
    - Although it is reported that lack of allocation concealment did not appear to bias the process, inadvertent bias is generally not apparent; this is why allocation concealment is considered an important protection against bias
- In spite of several limitations, the main outcome results are likely to reflect a social skills learning which the group intervention provided

Assessment: Adequate for evidence that group instruction by skilled leaders can improve the social communication skills for TBI patients in postacute care

Reference for PFIC:

Linscott RJ, Knight RG, Godfrey HPD. The Profile of Functional Impairment in Communication (PFIC): a measure of communication impairment for clinical use. Brain Injury 1996;10(6):397-412.